

**Notice of Allowability**

<b>Application No.</b> 10/803,177	<b>Applicant(s)</b> WAINWRIGHT ET AL.	
<b>Examiner</b> Nathan A. Bowers	<b>Art Unit</b> 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 12 July 2007.
2.  The allowed claim(s) is/are 1-14 and 79-85.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
    - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

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## DETAILED ACTION

### *Allowable Subject Matter*

Claims 1-14 and 79-85 are allowed.

As to independent claim 1, no prior art has been found to show or suggest a housing comprising a hemocyte lysates and an anti-flaking agent dried on a region of a conduit. Applicant has persuasively argued that the Tanaka reference teaches the permanent immobilization of a lysate onto a solid carrier. This teaches away from the claimed limitations which express that the lysate is solubilized and transported across the conduit upon interaction with a test sample. The Matuura (US 5318893) discloses the use of a freeze dried hemocyte lysate that is dissolved in a buffer and added to a solution that possibly contains microbial contaminants. Matuura, however, does not teach that the freeze dried hemocyte is applied to the walls of a cartridge. Furthermore, Tanaka and Matuura do not disclose the use of an anti-flaking agent.

As to independent claim 7, no prior art has been found to show or suggest a housing defining multiple fluid channels wherein one of the multiple channels includes a dried agent representative of a microbial contaminant. The Mahiout reference does not disclose the use of a positive control, or the use of reagents dried to the conduit walls. In Mahiout, reagents are disposed on a packing material within the conduit as opposed to being dried on the walls of the conduit. As indicated above, Applicant has persuasively argued that the cited prior art teaches the permanent immobilization of a lysate onto a solid carrier, and therefore teaches away from disposing lysates and microbial contamination representative agents so that they are solubilized and transported across the conduit upon interaction with a test sample.

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As to independent claim 79, no prior art has been found to show or suggest a housing comprising a conduit that is used to pump a sample across dried hemocyte lysate disposed within a channel. As already stated, Applicant has persuasively argued that the cited prior art teaches the permanent immobilization of a lysate onto a solid carrier, and therefore teaches away from solubilizing and transporting a hemocyte lysate across a conduit. Since the Mahiout reference teaches that fluids move through the system using capillary forces, Mahiout provides no suggestion that the system is compatible with a fluid pumping mechanism.

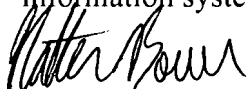
#### *Conclusion*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
NAB

  
GLADYS JP CORCORAN  
SUPERVISORY PATENT EXAMINER